

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1034436	<b>(X3) Date Survey Completed</b> 08/29/2018
<b>Name of Provider or Supplier</b> Pharr Kids Clinic	<b>Street Address, City, State</b> 832 Del Oro Ste #2, Pharr, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed on August 29, 2018 and found to be in compliance with the CLIA regulations. Recertification is recommended.
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing 6 month maintenance on the Medonic M series hematology analyzer. The findings were: 1. Review of the laboratory's policy titled, "Maintenance of Equipment and Instruments" approved by the laboratory director on September 13, 2010 stated, "For manufacturer's equipment, instruments or test systems cleared by the FDA, perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and document all maintenance performed." 2. Review of the manufacturer's instructions for the Medonic M series hematology analyzer (Art. no 1504248, May 20029) under, "Six (6) Month Cleaning" stated, "...Follow the instructions for the Boule Cleaning kit to clean the instrument, and the Six Month Cleaning Procedure takes approximately one hour and 15 minutes to complete." 3. Review of the laboratory's maintenance records from January 2017 to July 2018 revealed the 6 month maintenance as required by the manufacturer had not been documented as being performed. 4. Testing personnel four looked for other areas where the maintenance could have been documented but was unable to locate any other records. 5. An interview with testing personnel four (as listed on Form CMS-209) on 08/29/2018 at 14:30 hours confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p>

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on laboratory policy, review of manufacturer's instructions, review of calibration records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to print the pre-calibration report for the calibration performed in June 2018. The findings were: 1. Review of the laboratory's policy titled, "Calibration Verification Procedure" approved by the laboratory director on September 13 (year undecipherable) stated, "...For laboratory test procedures that are performed using Instruments, kits, or test systems that have been cleared by the FDA the laboratory must at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer." 2. Review of the manufacturer's instructions for the Medonic M series hematology analyzer (Article no. 1504248, May 2009) under Section 7, "Calibration" stated, "Prior to calibration print Calibration Log." 3. Review of the laboratory's calibration records from January 2017 to July 2018 revealed the laboratory failed to follow the manufacturer's instructions to print the Calibration log for the calibration performed on December 6, 2017 and June 22, 2018. 4. Interview with testing personnel four (as listed on Form CMS-209) on 08/29/2018 at 15:00 hours confirmed the findings. She confirmed that she was unsure if she had done it right.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of quality control records, review of patient final reports, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify that patient testing was performed when quality control failed for both testing modes on the Medonic M series hematology analyzer on 11/24/2017. The findings were: 1. Review of quality control records from January 2017 to July 2018 revealed that on November 24, 2017 quality control testing failed on both modes for the Medonic M series hematology analyzer. 2. The laboratory's quality

assurance records for November 2017 failed to identify that both modes failed and patient testing was performed. 3. Review of patient charts from November 24, 2017 revealed the following four patients were tested when quality control testing failed: Patient 1 Date of Birth: 10-09-2014 Patient 2 Date of Birth: 05-25-2002 Patient 3 Date of Birth: 02-06-2014 Patient 4 Date of Birth: 07-14-2014 4. Interview with testing personnel four (as listed on Form CMS-209) on 08/29/2018 at 16:00 hours confirmed the findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on laboratory policy, review of the laboratory's submitted Form CMS-209, review of personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform two competency assessments for testing person three (as listed on Form CMS-209) their first year of patient testing in 2017. The findings were: 1. Review of the laboratory's policy titled, "Testing Personnel Initial Training and Competency Program" (no approval date) stated, "Purpose: Testing Personnel performance is evaluated initially after completed training, within 6 months of hire and annually thereafter to ensure that they are performing the various procedures in a consistent manner and are competency to perform their duties and responsibilities as required by federal regulations..." 2. Review of the laboratory's submitted Form CMS-209 approved by the laboratory director on August 21, 2018 revealed the laboratory identified 6 testing persons. 3. Review of the personnel files for testing personnel three (as listed on Form CMS-209) revealed she had a hire date of June 5, 2017 and was performing testing as of the date of the survey, August 29, 2018. 4. Further review of the records revealed testing personnel three had a competency assessment dated March 15, 2018 that was marked as, "Initial." No other competency assessments were available for review to determine if she a second competency assessment during her first year of patient testing. 5. Interview with testing personnel four (as listed on Form CMS-209) on 08/29/2018 at 13:30 hours in the medical records room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services